THE CLAIMS

We claim:

1. A medical device having at least an expandable portion which is insertable or implantable into a body lumen of a patient,

wherein at least a part of the expandable portion is covered with a sponge coating to form an exposed outermost surface for release of at least one biologically active material, and

wherein the sponge coating comprises a non-hydrogel polymer having a plurality of voids, wherein the voids contain at least one biologically active material.

2. The medical device of claim 1 wherein the voids are formed by eluting a particulate material from the polymer.

3. The medical device of claim 1 wherein the voids are greater than about 60% of the volume of the sponge coating.

4. The medical device of claim 1 further comprising means for infusing the biologically active material into the voids.

5. The device of claim 1 wherein the device is a catheter for delivering the biologically active material and wherein the expandable portion is expandable in response to inflation pressure to substantially fill the cross-section of the lumen and engage the tissue of the lumen.

6. The device of claim 5 wherein the expandable portion is inflated by an inflation lumen connected to a balloon having pores.

7. The device of claim 6 wherein the balloon is capable of containing the biologically active material which can be released through the pores and infused into the voids.

8. The device of claim 5 wherein the expandable portion further comprises a perfusion lumen for sustained infusion of the biologically active material into the voids and inflation of the expandable portion.

9. The device of claim 5 which further comprises control means for synchronizing the deflation of the expandable portion and the infusion of the biologically active material into the voids.

10. The device of claim 1 wherein the polymer comprises an elastomer.

11. The device of claim 10 wherein the elastomer is selected from the group consisting of silicones, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, and EPDM rubbers.

polyisobutylene and its copolymers

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12. The device of claim 5 wherein the biologically active material is heparin.

13. The device of claim 5 wherein the catheter is capable of delivering a stent for implantation in the body lumen.

14. A catheter for delivering a biologically active material to a desired location of a body lumen of a patient comprising an expandable portion which is insertable or implantable into a body lumen, wherein the expandable portion is expandable in response to inflation pressure to fill the cross-section of the lumen and engage the tissue of the lumen and wherein the expandable portion comprises:

a) a reservoir defined by a membrane having a plurality of pores therein, and wherein the reservoir is capable of containing the biologically active material and is connected to a reservoir lumen for filling the reservoir with the biologically active material;

b) a sponge coating for release of at least one biologically active material disposed about the membrane, wherein the sponge coating comprises a non-hydrogel polymer having a plurality of voids; and

c) means for infusing the biologically active material into the voids.

15. The catheter of claim 14 wherein the voids are formed by eluting a particulate material from the polymer.

16. The catheter of claim 14, wherein the voids are greater than about 60% of the volume of the sponge coating.

17. The catheter of claim 14 wherein the infusion means comprises an inflation lumen connected to a balloon disposed wherein the reservoir.

18. The catheter of claim 14 wherein the expandable portion further comprises a perfusion lumen for sustained infusion of the biologically active material into the voids and inflation of the expandable portion.

19. The catheter of claim 14 which further comprises control means for synchronizing the deflation of the expandable portion and the infusion of the biologically active material into the voids.

20. The catheter of claim 14 wherein the polymer comprises an elastomer.

21. The catheter of claim 20 wherein the elastomer is selected from the group consisting of silicones, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, and EPDM rubbers.

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22. The catheter of claim 14 wherein the biologically active material is heparin.

23. A method of making a medical device having at least an expandable portion for insertion or implantation into the body of a patient, wherein the portion has a surface which is adapted for exposure to body tissue of the patient and wherein at least a part of the surface is covered with a coating to release at least one biologically active material therefrom, the method comprising:

a) forming a sponge coating by

i) applying a composition comprising a non-hydrogel polymer and a particulate material to the surface and

ii) exposing the surface to a fluid to elute the particulate material from the polymer, and

b) loading the sponge coating with the biologically active material.

24. The method of claim 23 wherein the fluid is a solvent.

25. The method of claim 23 wherein the fluid is a body fluid.

26. The method of claim 23 wherein the particulate material is eluted *in vivo* while the device is inserted or implanted in the body to form a plurality of voids in the sponge coating and wherein the voids are greater than about 60% of the volume of the sponge coating.

27. The method of claim 24 wherein the particulate material is a biologically active material.

28. The method of claim 23 wherein the biologically active material is loaded into the sponge coating by dipping the surface into a composition comprising the biologically active material.

29. The method of claim 23 wherein the polymer comprises an elastomer.

30. The method of claim 29 wherein the elastomer is selected from the group consisting of silicones, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, and EPDM rubbers.

31. The method of claim 23 wherein the biologically active material is heparin.

32. The method of claim 23 wherein the particulate material is selected from the group consisting of polyethylene oxide, polyethylene glycol, polyethylene oxide/polypropylene oxide copolymers, polyhydroxyethyl methacrylate, polyvinylpyrrolidone, polyacrylamide and its copolymers, salts, sugars, and elutable biologically active materials.

33. The method of claim 23 further comprising curing the composition prior to exposing the surface to a solvent to elute the particulate material from the polymer.

34. A method of delivering a biologically active material to a desired location of a body lumen of a patient comprising

a) forming a sponge coating on a surface of an expandable portion of a medical device for insertion or implantation into the body of a patient, wherein the device comprises means for expelling the biologically active material from the device, and wherein the expandable portion has a surface which is adapted for exposure to body tissue of the patient, by

i) applying a composition comprising a non-hydrogel polymer and a particulate material to the surface and

ii) exposing the surface to a solvent to elute the particulate material from the polymer to form a plurality of voids therein,

b) loading the sponge coating with the biologically active material, by expelling the biologically active material from the device and

c) inflating the expandable portion at the desired location to deliver the drug.

35. The method of claim 34 which further comprises deflating the expandable portion and simultaneously expelling the biologically active material into the voids.

36. The method of claim 34 wherein the particulate material is eluted *in vivo* while the device is inserted or implanted in the body to form a plurality of voids in the sponge coating, and wherein the voids are greater than about 60% of the volume of the sponge coating.

37. The method of claim 36 wherein the particulate material is a biologically active material.

38. A stent prosthesis having at least an expandable portion which is insertable or implantable into a body lumen of a patient,

wherein at least a part of the expandable portion is covered with a sponge coating to form an exposed outermost surface for release of at least one biologically active material, and

wherein the sponge coating comprises a non-hydrogel polymer having a plurality of voids, wherein the voids contain at least one biologically active material.

39. The stent of claim 38 wherein the stent is a self-expanding stent.

40. The stent of claim 38 wherein the stent is a balloon-expanding stent.

41. The stent of claim 38 wherein the voids are formed by eluting a particulate material from the polymer.

42. The stent of claim 38 wherein the voids are formed while the stent is inserted or implanted in the body lumen.

43. The stent of claim 38 wherein the voids are greater than about 60% of the volume of the sponge coating.

44. The stent of claim 38 wherein the polymer comprises an elastomer.

45. The device of claim 44 wherein the elastomer is selected from the group consisting of silicones, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, and EPDM rubbers.

46. The device of claim 38 wherein the biologically active material is heparin.